

Budesonide 3mg Delayed-Release Capsule (Entocort EC)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Budesonide 3mg Oral capsule (Brand Name, Entocort EC 3mg Capsule) is a medication belonging steroid class. Budesonide 3mg Oral capsule (Brand Name, Entocort EC 3mg Capsule) is approved for the treatment or maintenance of clinical remission for certain individuals with mild to moderate active Crohn's disease. Budesonide is also available in several other products and formulations, including intranasal inhalation, oral inhalation, rectally, or orally. The other budesonide products are indicated and used for conditions including Crohn's disease, ulcerative colitis, certain kidney conditions to lower the risk of worsening kidney problems, and sometimes may be used for other purposes. Depending on the specific product or formulation, the use and effectiveness of budesonide varies. Please refer to [Appendix A](#), Table 1 for a list of available budesonide oral tablets & capsules, and their approved indications and usage.

Definitions

"Autoimmune Hepatitis" refers to a condition in which the liver is attacked by the body's immune system and causes it to become inflamed, potentially causing cirrhosis (scarring of the liver) and liver failure.

"Crohn's Disease" refers to a chronic inflammatory condition that affects the gastrointestinal (GI) tract. The symptoms can come and go, and can affect any part of the GI tract, but usually in the small intestine and the beginning of the large intestine. It is among a group of diseases commonly referred to as inflammatory bowel disease (IBD).

"Microscopic Colitis" refers to conditions, known as lymphocytic colitis and collagenous colitis, which causes watery diarrhea.

"Ulcerative Colitis" refers to a chronic inflammatory condition that affects the colon (large intestine) and rectum. It is among a group of diseases commonly referred to as inflammatory bowel disease (IBD).

Clinical Indications

Medical Necessity Criteria for Initial Authorization

The Plan considers Budesonide 3mg Oral capsule medically necessary when ALL the following criteria are met for the applicable indication listed below:

Crohn's Disease

1. The member is 8 years or older; *AND*
2. The member has a documented diagnosis mildly to moderately active Crohn's disease; *AND*
3. Chart documentation and supporting laboratory test results are provided for review to substantiate the above listed requirements.

Autoimmune Hepatitis

1. The requested medication is prescribed by or in consultation with a hepatologist; *AND*
2. The member has a documented diagnosis of autoimmune hepatitis; *AND*
3. The member meets ALL of the following:
 - a. No evidence of acute severe autoimmune hepatitis; *or*
 - b. No evidence of acute liver failure; *or*
 - c. No evidence of cirrhosis; *AND*
4. The member is unable to use or has tried and failed prednisone/prednisolone; *AND*
5. Chart documentation and supporting laboratory test results are provided for review to substantiate the above listed requirements.

Microscopic (lymphocytic and collagenous) Colitis

1. The member has a documented diagnosis of microscopic colitis, defined as ONE (1) of the following:
 - a. Greater than or equal to 3 stools daily; *or*
 - b. Greater than equal to 1 watery stool daily; *AND*

2. Chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria is met, Budesonide 3mg capsules will be approved for up to 16 weeks.

Medical Necessity Criteria for Reauthorization

Crohn's Disease

Reauthorization for up to 3-months will be granted if the member has recent chart documentation (within the last 3 months) demonstrating a clinical improvement (e.g., clinical remission, Crohn's Disease Activity Index (CDAI) score of 150 or less, quality of life improvement) in symptoms from the previous course of therapy with the requested medication.

Autoimmune Hepatitis

Reauthorization for up to 6-months will be granted if the member has recent chart documentation (within the last 3 months) demonstrating a clinical improvement (e.g., clinical remission, prevented further progression of liver damage) in symptoms from the previous course of therapy with the requested medication.

Microscopic (lymphocytic and collagenous) Colitis

Reauthorization for up to 12-months will be granted if the member has recent chart documentation (within the last 3 months) demonstrating a clinical improvement (e.g., clinical remission, histological improvement, quality of life improvement) in symptoms from the previous course of therapy with the requested medication.

Experimental or Investigational / Not Medically Necessary

Budesonide 3mg Oral capsule for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

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Appendix A

Table 1: Budesonide Oral Tablet & Capsules for Inflammatory Bowel Disease

Product	Generic Availability	FDA-approved Indications and Usage
Entocort 3mg EC Capsule Delayed Release Particles, Oral	Yes	<ol style="list-style-type: none"> 1. The treatment of mild to moderate active Crohn's disease involving the ileum and/or the ascending colon, in patients 8 years and older 2. The maintenance of clinical remission of mild to moderate Crohn's disease involving the ileum and/or the ascending colon for up to 3 months in adults.
Ortikos 6mg & 9mg Capsule Extended Release 24 Hour, Oral	No	<ol style="list-style-type: none"> 1. The treatment of mild to moderate active Crohn's disease involving the ileum and/or the ascending colon in patients 8 years of age and older 2. The maintenance of clinical remission of mild to moderate Crohn's disease involving the ileum and/or the ascending colon for up to 3 months in adults.

Uceris 9mg Tablet Extended Release 24 Hour, Oral	Yes	1. The induction of remission in patients with active, mild to moderate ulcerative colitis.
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Table 2: Common Treatment Regimens using Budesonide 3mg Delayed-Release Capsule (Entocort EC)

Condition	Induction	Maintenance
Crohn's Disease	9 mg once daily in the morning for up to 8 weeks; a second 8-week (16 weeks of continuous therapy) course with the drug may be beneficial in some patients	6 mg once daily for up to 3 months
Autoimmune hepatitis	3 mg three times daily	May reduce to 3 mg twice daily after remission, then slowly taper over 6 months to maintenance dose of 3 mg daily
Microscopic Colitis (also referred to as lymphocytic colitis or collagenous colitis)	9 mg once daily for 6 to 8 weeks; a tapering schedule for 8 weeks has been used in clinical trials	6 mg once daily, then taper to the lowest effective dose and continue for 6 to 12 months OR 3 mg/day alternating with 6 mg/day over 12 months

Clinical Guideline Revision / History Information

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